

--52. (New) The method of claim 31, wherein the formation of the filter material has a pore size of 0.08 to 0.15 μm .--

REMARKS

Claims 1, 3-13 and 15-52 are pending in the application. Claim 2 and 14 have been canceled without prejudice. Claims 1, 3-13, and 15-33 have been amended. Claims 34-52 have been added. The specification has been amended in order to include a brief description of the drawings.

Support for these amendments is found throughout the original specification and claims as filed and it is respectfully submitted that no new matter has been added by virtue of this amendment.

Objection Under 37 C.F.R. § 1.75

In the Office Action, claims 4-21 and 25-33 were rejected for being in improper form. In response, the claims have been amended in order to remove multiple dependent claims which depend on other multiple dependent claims as pointed out by the Examiner.

Accordingly, applicant respectfully requests removal of this rejection and examination of these claims on the merits.

Rejection Under 35 U.S.C. § 112, First Paragraph

In the Office Action, claims 1-3 and 22-24 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the claims, while being enabling for liposomes, do not reasonably provide enablement for claims "recited in very vague and confusing terms." In order to expedite the prosecution of this application, claims 1-3 and 22-24 have been revised to conform with U.S. patent practice. The claims now specifically refer to transfersomes, which term has support throughout the specification. The Examiner's attention is respectfully directed to page 5 of the specification, lines 1-16, where differences between transfersomes and liposomes are explained.

Accordingly, it is requested that the Examiner withdraw the rejection of claims 1-3 and 22-24 under 35 U.S.C. §112, first paragraph.

Rejection of Claims under 35 U.S.C. § 112, Second Paragraph

In the Office Action, the Examiner rejected claims 1-3 and 22-24 under 35 U.S.C. § 112, second paragraph, on the grounds that the independent claims are unclear as to what is being claimed. The Examiner suggested that the claims be thoroughly revised and restructured in accordance with U.S. practice.

In order to expedite the prosecution of this application, claims 1-3 and 22-24 have been revised in accordance with U.S. practice, as suggested by the Examiner.

Specifically, the claims have been amended in order to remove the terms “membrane-like” and “and the like”, “usually water”, “especially”, “for example”, “such as” and “otherwise controlled”. Method claim 22 has been amended to recite proper method steps “a” through “d”.

Accordingly, it is requested that the Examiner withdraw the rejection of the claims under 35 U.S.C. §112, second paragraph, be removed.

Rejection of Claims under 35 U.S.C. § 102

In the Office Action the Examiner rejected claims 1-3 and 22-24 under 35 U.S.C. § 102 on the grounds of being anticipated over EP 0220 797 or Roberts (4,921,706) or Mayer (BBA, 1986), Blume (J of Liposome Research, 1992) or EP 0 707 847 or EP 0704 206. The Examiner stated that EP 797 “discloses liposomes containing a drug, an amphiphilic lipid and a surfactant in instant amounts and a method of preparation.” The Examiner further stated that Roberts, Mayer, EP 847 and EP 206 “all teach liposomes containing an amphiphilic lipid and a method of preparation” and stated that Blume and EP 160 “teach transfersomes and a method of preparation.”

These rejections are respectfully traversed as the present invention is not anticipated by any of the above references.

At the very least, it is respectfully submitted that none of these references disclose transfersomes which undergo sufficient deformation to transport through skin or mucous membranes due to the selection of at least two amphiphilic lipid components which differ in their solubility in the transfersome medium by a factor of at least 10. Further, these references do not teach or disclose transfersomes which undergo sufficient deformation to transport through skin or mucous membranes without being solubilized.

Accordingly, it is respectfully submitted that the rejections under 35 U.S.C. §102 have been obviated and should be removed.

Rejection of Claims under 35 U.S.C. §103

In the Office Action the Examiner rejected claims 1-3 and 22-24 under 35 U.S.C. § 103 on the grounds of being obvious over the references cited above with respect to the § 102 rejections. The Examiner stated the following:

“...the references teach liposomes or transfersomes containing a drug an amphiphilic lipid and a surfactant in instant amounts and a method of preparation. It is unclear whether the references teach all of the instant functional parameters. In case they are different, in the absence of showing the criticality, they are deemed to be parameters manipulated by an artisan to obtain the best possible results.”

This rejection is respectfully traversed. It is respectfully submitted that none of these references disclose transfersomes which undergo sufficient deformation to transport through skin or mucous membranes due to the selection of at least two amphiphilic lipid components which differ in their solubility in the transfersome medium by a factor of at least 10. Further, these

references do not teach or disclose transfersomes which undergo sufficient deformation to transport through skin or mucous membranes without being solubilized.

Further, none of the cited references hint or suggest that choosing two transfersome components can be manipulated in the manner claimed in order to obtain transfersomes which undergo sufficient deformation to transport through skin or mucous membranes.

The Examiner takes the position that these parameters would be manipulable to one skilled in the art in order to arrive at the present invention. However, it is respectfully submitted that the Examiner has failed to provide evidence to support his position. The Examiner has not introduced any reference which teaches that, e.g. one can select at least two components which differ in their solubility in the transfersome medium by a factor of at least 10, in order to provide transfersomes which undergo sufficient deformation to transport through skin or mucous membranes. Absent such evidence, the Examiner's rejection cannot stand.

Accordingly, it is respectfully submitted that the rejections under 35 U.S.C. §1032 have been obviated and should be removed.

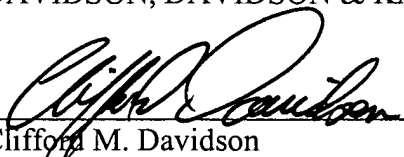
Conclusion

It is respectfully submitted that the rejections in the Office Action have been obviated and the pending claims are now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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A handwritten signature in cursive script, appearing to read "Clifford M. Davidson", is written over a horizontal line.

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